# MediVital®

## PRESSURE REGULATORS INTEGRATED WITH CYLINDER VALVES

EN

INSTRUCTION FOR USE


openhouse
the solution provider

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# 1. FOREWORD

The product complies with the essential requirements of 93/42/EEC Medical Device Directive and Transportable Pressure Equipment Directive 2010/35 EU. The combination valve is designed according to EN ISO 10524-3 and EN ISO 10297 standards.

# 2. INTENDED USE

MediVital® Combination Valves are designed to be fitted to gas cylinders used for medical gases. These combination valves together with a gas cylinder form gas packages used either as gas supply point for medical devices (anaesthetic devices, ventilating devices, incubators etc.) or for direct gas supply to a patient's breathing mask or cannula.

GCE Combination Valves are intended to be used with the following medical gases:

- Oxygen
- Nitrous oxide
- Air for breathing
- Helium
- Carbon dioxide
- Mixtures of the gases listed above

# 3. OPERATIONAL, TRANSPORT AND STORAGE SAFETY REQUIREMENTS

**KEEP THE PRODUCT AND ITS ASSOCIATED EQUIPMENT AWAY FROM:**

- Heat sources (fire, cigarettes,...)
- Flammable materials
- Oil or grease (take a great care in the use of hand creams)
- Water
- Dust

**The product and its associated equipment must be prevented from tipping over, turning over or falling.**

**Always maintain oxygen cleanliness standards.**

**Only use the product and its associated equipment in well ventilated area.**

Before the first use the product shall be kept in its original package. If removed from service (for transport, storage) GCE recommends using the original package (including inner packing materials).

National laws, rules and regulations for medical gases, accident prevention and environmental protection must be observed.

| OPERATING CONDITIONS | | STORAGE AND TRANSPORT CONDITIONS | |
|---|---|---|---|
| | -20* / +65 °C | | -40 / +70 °C |
| | 10 / 100 % | | 10 / 100 % |
| | 600 / 1200 mbar | | 600 / 1200 mbar |

*for inner tightness of the shut-off valve, during transport and storage of the combination valve mounted on a cylinder, the valid lower temperature limit is -40°C.

**In case of combination valve storage at temperature below -20°C do not use the combination valve until its temperature reaches at least -20°C.**

**For the combination valves designed to be used with mixture of gases $O_2$+$N_2O$, the lowest operating temperature is +5°C. In normal use of the combination valve, frosting can appear on the combination valve surface, which is caused by the gas inside the combination valve when high pressure in the combination valve cooling when high pressure gas is being reduced to low pressure (Joule-Thomson effect). Check that all patient associated equipment connected to the combination valve is via a hose of at least 2 metres length.**

**$O_2$+$N_2O$ mixtures are temperature sensitive. $N_2O$ begins to separate out from the mixture if the temperature falls below about -6°C. A homogenous mixture is again obtained when the temperature has raised above 10°C and the cylinder was agitated. Before use, to ensure it is properly mixed, cylinders should be stored horizontally for 24 hours at a temperature above 10°C. If this is not practicable, before use the cylinders must be maintained at a temperature above 10°C for at least 2 hours and then completely inverted three times or placed in warm water at body temperature for 5 minutes and then completely inverted three times.**



## 4. PERSONNEL INSTRUCTIONS AND TRAINING

The Medical Devices Directive 93/42/EEC states that the product owner must ensure that all personnel using the product are provided with the instructions for use and are fully trained in the use of the equipment .

**Do not use the product without proper training! Trainees must be trained by an experienced person who has been authorised by the manufacturer and has an appropriate education, knowledge and experience.**

For further information about training of responsible personnel, please contact GCE.

# 5. PRODUCT DESCRIPTION

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Combination valve combines the function of shut-off valve of a high pressure gas cylinder and pressure regulator for the use with medical gases. Gas from the cylinder is first controlled by the main shut-off valve and then passed through the pressure regulator and finally delivered to the patient through the flow outlet or the pressure outlet. Outlet pressure is fixed by the manufacturer and each combination valve is provided with a low-pressure relief valve to protect against pressure regulator failure.

There are three basic alternatives:

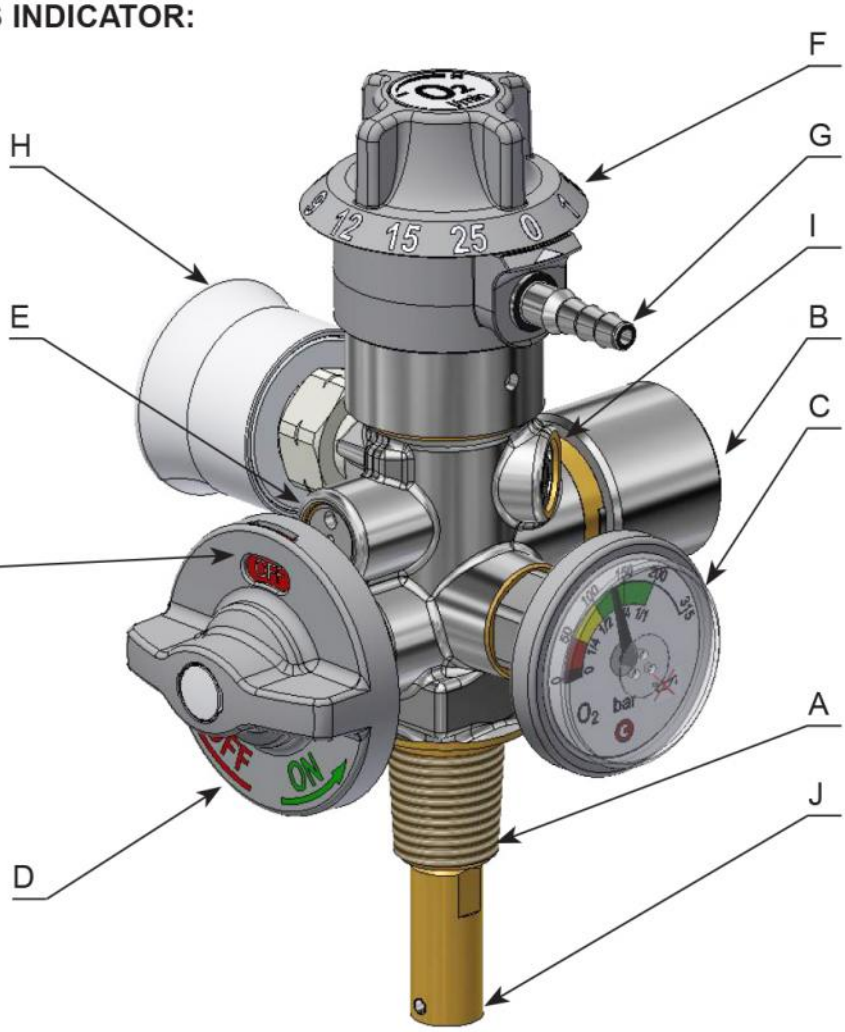
- combination valve with quick-coupler outlet, the outlet pressure is constant, and flow is not controlled by the combination valve
- combination valve with outlet via calibrated nozzles, outlet flows is controlled by the combination valve and can be changed by the control head,
- the combination valve of both alternatives.

**SHUT OFF VALVE STATUS INDICATOR:**

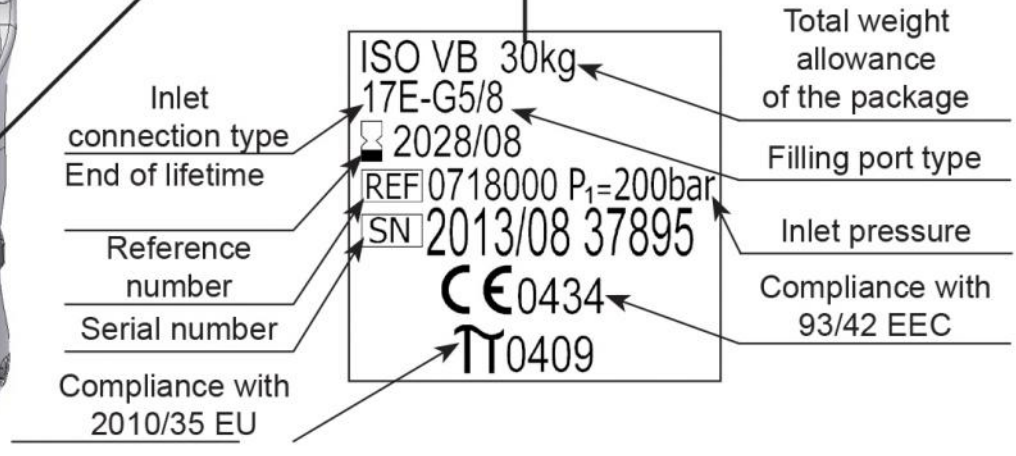
fully OPEN
green colour


fully CLOSED
red colour


partly OPEN
red / green colour




**Marking detail**



**A – INLET STEM**

The combination valve is fitted to gas cylinder by a threaded inlet stem. The inlet stem can be taper threaded or parallel threaded with different size depending on the cylinder size and material.

**B – FILLING PORT**

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A filling port is provided for filling the gas cylinder at a filling station, it has no function for patient use. It includes a non-return valve (NRV). The NRV means that special filling adaptors are required to vent gas from the cylinder during the filling process (venting and/or vacuuming of cylinders).

**C – INLET PRESSURE INDICATOR**

Inlet pressure indicator is intended to indicate amount of gas in the gas cylinder. The pressure indicator is of an active type which means it indicates amount of gas in the gas cylinder whether the shut-off valve is opened or closed.

**D – SHUT-OFF VALVE**

The combination valve is provided with a shut-off valve to isolate the gas in the cylinder from the rest of combination valve functions. It must be opened during cylinder filling and patient's therapy. Part of the handwheel is an indicator showing open/close status of the shut-off valve.

⚠ **The shut-off valve open/close status indicator is for guidance only. The shut-off valve may not be fully off when closed status is showing. Fully closed status has to be checked by ensuring the shut-off valve is turned to OFF position (clockwise) and gas supply to the outlets has stopped.**

⚠ **The shut-off valve must not be used in the "partly ON" status because even though gas is supplied to the outlets, the flow can be limited due to insufficiently opened shut-off valve.**

**E – RESIDUAL PRESSURE VALVE**

Combination valve is equipped with a residual pressure valve with function to retain a minimum positive pressure in the gas cylinder to avoid contamination of the cylinder content by atmospheric air. During cylinder gas ventilation through the filling port the residual pressure valve is by passed.

**F, G – FLOW CONTROL HEAD “F” AND FLOW OUTLET “G” (OPTION)**

Combination valve can be delivered with a flow control head “F”.This function is used to supply adjustable gas flow rates (l/min) at atmospheric pressure directly to a patient through the flow outlet “G”, for instance through a cannula or a facemask. The flow outlet “G“ is equipped with hose fitting (hose nipple) or a threaded type (for accessories to be connected via threaded connection).

Movement of the flow outlet ‘G’ is normal due to the method of fixing in the main body. It doesn’t indicate a faulty flow outlet.

**H – PRESSURE OUTLET OR QUICK COUPLER (OPTION)**

The combination valve may be fitted with a pressure outlet. The pressure outlet is supplied with gas direct from the low-pressure part of the combination valve and it is fitted with a gas specific medical quick coupling connector also called “quick coupler”. The user can connect another piece of equipment to this outlet with a gas specific male probe (see appendix nr. 2). The quick coupler self seals when the male probe is disconnected. This outlet is for supplying gas at a controlled pressure to power medical devices, for instance medical ventilator.

**I - PRESSURE RELIEVE VALVE OF LOW PRESSURE PART**

Pressure relieve valve secures the low pressure part of combination valve and connected medical devices against over-pressure. If the gas pressure is decreased enough after the pressure relieve valve activation, it will closes itself.

**J - EXCESS FLOW DEVICE OR DIP TUBE (OPTION)**

Excess flow device ensures safe ventilation of gas from gas cylinder in case the combination valve is broken above inlet stem (e.g. cylinder fall). Dip tube does not have such function. Excess flow device and dip tube are to avoid contamination from cylinder entering the

combination valve .

**PRESSURE RELIEVE DEVICE OF HIGH PRESSURE PART - BURSTING DISC (OPTIONAL)**
The high pressure relieve device is intended to protect the cylinder and high pressure part of combination valve against damage caused by increased cylinder pressure. If the pressure relieve device has been activated, it will not reseal and the combination valve must be taken out of service for repair (see Chapter 9).

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**Note: Colour of the product (especially guard, flow control head and shut-off valve) does not have to match the gas colour coding.**

# 6. USE OF PRODUCT

## 6.1. OPERATIONS PERFORMED BY THE PROVIDER, DISTRIBUTOR - FILLING STATION

### 6.1.1 GUARD

A valve guard should be provided where possible. If the used guard comply with EN ISO 11117 standard the package of combination valve with guard and gas cylinder must meet the drop test requirements according to EN ISO 10524-3.

The total weight of the package as marked on the combination valve must not be exceeded if the GCE guard is used, the guard does not comply to EN ISO 11117 or no guard is used.

**Note: Total weight of package includes weight of combination valve , weight of cylinder filled with gas to max. limit and all permanently fixed parts.**

The guard must allow easy access to all controlling elements of the combination valve , must not inhibit connection of medical devices and other accessories to the combination valve outlet (ex. filling adaptor), must not influence any functions of combination valve (ex. pressure relieve valve) and inhibit legibility of labels and marking.

⚠ **There is a higher risk of damage if the combination valve is used without a guard.**

### 6.1.2 FITTING THE COMBINATION VALVE TO A GAS CYLINDER

Observe oxygen cleanliness standards during installation.

- Check combination valve and gas cylinder for visible damage (especially inlet stem thread of the combination valve and thread of gas cylinder).
- Check combination valve and gas cylinder for contamination. If needed, apply the cleaning procedure according to chapter 8. For gas cylinder cleaning, refer to the cylinder manufacturer cleaning procedure.
- Check if the total life time of the combination valve and the gas cylinder has not been exceeded.
- Ensure that the product inlet stem is compatible with the gas cylinder.
- Check the presence & the integrity of seals / sealing materials (PTFE tape, O-ring) on inlet stem.
- Check that the gas cylinder pressure rating is higher than inlet pressure of the combination valve .
- At variant with GCE guard take off the filling port protective cover.
- Ensure that fitting equipment does not interfere with/or damage the guard and other parts of the combination valve or cylinder.
- Assembly combination valve on gas cylinder To tighten the combination valve in cylinder use only the square surfaces of the combination valve body. The across flat size of square surface is 26 mm. During fitting of combination valve to the cylinder follow torque figures specified in EN ISO 13341.
- Return filling port protective cover on the combination valve .

⚠ **The product is only designed for use with gas specified on its marking. Never try to fit to a gas cylinder specified for different gas type.**

⚠ **If you suspect that inner parts of the combination valve have been contaminated, it**

**must be withdrawn from the service immediately.**

**Do not exceed the maximum torque allowed for the cylinder. Excessive torque may damage the combination valve thread preventing its reuse. Certain types of cylinders may require a torque lower than specified in EN ISO 13341. Check max. allowed torque value with your cylinder supplier.**



**Multiple reassembly can damage inlet stem thread.**

**Take care not to damage external components of combination valve for instance inlet gas pressure indicator.**

### 6.1.3 FILLING OPERATIONS

**Observe oxygen cleanliness standards during filling.**

**Use genuine GCE filling adaptors only. Other filling adaptors may damage the non-return valve in the filling port and impact the safety of the product.**

#### 6.1.3.1 Inspection before filling

- Check if all labels and markings are legible and undamaged.
- Remove protective cover from the filling port. Some types of covers are permanently connected to the combination valve or guard. This is to prevent its loss and such connection should not be broken.
- Check combination valve and filling adaptor for damage.
- Check combination valve and filling adaptor for contamination. If needed proceed with cleaning procedure according to chapter 8.
- Check that the service or the total life time of the GCE product and gas cylinder has not been exceeded.
- If a bursting disk is part of the combination valve , check that not damaged.
- Check that the filling port is compatible with the filling adaptor (gas / type).
- Check the preset filling pressure - The filling pressure (settled pressure at 15°C) shall not exceed rated combination valve inlet pressure.

**If you have a suspect that inner parts of the combination valve have been contaminated, it must be withdrawn from the service immediately.**

#### 6.1.3.2 Combination valve venting

**A. Venting of combination valve through flow control head:**

- Ensure the shut-off valve is closed.
- Set flow control head in maximal position - ensure that flow control head engages correctly.
- Wait until the combination valve is completely vented.
- Set flow control head in position "0" - ensure correct position of flow control head.

**B. Venting of combination valve through gas pressure outlet:**

- Ensure the shut-off valve is closed.
- Insert quick-coupler probe in the combination valve quick coupler (refer to appendix Nr. 2 to get information about connecting / disconnecting procedure of quick coupler type on your product).
- Wait until the combination valve is completely vented.
- Disconnect quick coupler probe.

**Venting through the combination valve quick-coupler must only be performed with appropriate quick coupler probe to prevent combination valve damage.**

#### 6.1.3.3 Fitting the filling adaptor

- Connect the filling adaptor using max. tightening torque of 3,5 Nm.

**To prevent combination valve damage, pressure inside the combination valve must be**

**vented according to 6.1.3.2 before fitting the filling adaptor.**

**Pneumatic or electric wrench can be used with some types of filling adaptors. However these must be equipped with a torque limiting device to ensure tightening torque will not exceed 3,5 Nm.**

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### 6.1.3.4 Venting of residual gas from cylinder

**A. Cylinder venting through flow control head:**

- Slowly open shut-off valve handwheel (anticlockwise) until fully open - after approx. 1 turn (see indication in picture chapter 5).
- Set flow control head to maximal position - ensure that flow control head engages correctly.
- Wait until the cylinder has vented completely.
- Close the shut-off valve (clockwise). Do not use excessive torque (max. closing torque is 5 Nm).
- Set flow control head in "0" position.

**B. Cylinder venting through gas pressure outlet:**

- Slowly open shut-off valve handwheel (anti-clockwise) until fully open - after approx. 1 turn (see indication in picture chapter 5).
- Insert quick-coupler probe in the combination valve quick coupler (refer to appendix nr. 2 to get information about connecting / disconnecting procedure of quick coupler type on your product).
- Wait until the cylinder has vented completely.
- Close the shut-off valve (clockwise). Do not use excessive torque (max. closing torque is 5 Nm).
- Disconnect quick coupler probe.

**Note: Venting of the cylinder by following steps A or B can be performed prior to fitting the filling adaptor. Venting of the cylinder by following steps 'C' and 'D' requires the filling adapter to be fitted to the combination valve first according to chapter 6.1.3.3.**

**C. Venting of the residual gas from cylinder through a filling port**

- Ensure all lines of the filling manifold are correctly connected to the combination valve filling ports
- Ensure the manifold vent valve and isolation valve is closed
- Slowly open the combination valve shut-off valve handwheel (anti-clockwise) until fully open - after approx. 1 turn (see indicator in picture chapter 5)
- After pressure between cylinders and filling manifold is settled open manifold vent valve
- Wait until the residual gas is completely vented from all the cylinders
- Close manifold vent valve

**D. Vacuuming of cylinder**

If it is necessary to vacuum the cylinder to reach the required gas purity, this is possible through the combination valve filling port after venting of the cylinder

- Connect combination valves to the filling manifold and vent cylinders according to 'C' above
- Ensure manifold vent and isolation valves are closed
- Ensure the combination valve shut-off valve is fully open
- Open manifold vacuum valve
- When required vacuum level has been reached close manifold vacuum valve

**Gas cylinder venting must be done in well vented area to prevent saturation of ambient atmosphere with oxygen that would increase risk of ignition.**

**Sudden opening could result in a danger of fire or explosion arising from oxygen pressure shocks. Insufficient opening of the shut-off valve could reduce actual flow delivered.**

**Make sure that during venting of the residual gas the surface temperature of combination valve and cylinder does not exceed limited operational conditions. If this happens the combination valve must be allowed time to recover temperature before filling is started. The level of temperature change is dependant on many factors (residual**

**pressure, ambient temperature, size and material of the cylinder, type of gas, speed and duration of venting)**

⚠ **Venting through the combination valve quick-coupler must only be performed with appropriate quick coupler probe with inner hole of 1 mm to limit flow prevent combination valve damage.**



#### 6.1.3.5 Cylinder filling

- Ensure the shut-off valve on combination valve is fully open.
- Proceed with filling the gas cylinder.
- Close shut-off valve after filling. Do not use excessive torque (max. closing torque is 5 Nm).
- Vent the filling connections (including high pressure filling hose).
- Disconnect filling adaptor.
- Before releasing the gas package for patient use, perform functional and leak-tight checks (refer to appendix Nr. 3 “Post filling checks”).
- After completion of tests according to appendix Nr. 3, return the filling port protective cover. Use only original GCE protective cover.

⚠ **Pressure in the filling connections during disconnection of the filling adaptor or open shut-off valve of combination valve may cause personnel injury or damage to the combination valve or filling adaptor.**

⚠ **Make sure that during filling the surface temperature of combination valve and cylinder does not exceed the allowed maximal limits. Temperature increase is affected by size and material of cylinder, type of gas, duration of filling and filling pressure.**

### 6.1.4 REMOVAL OF COMBINATION VALVE FROM CYLINDER

- Observe oxygen cleanliness standards during removal.
- Perform cylinder venting – follow Chapter 6.1.3.4, step A or B.
- Remove filling port protective cover. Some types of covers are permanently connected to the combination valve or guard. This is to prevent its loss and such connection should not be broken.
- Ensure the combination valve shut-off valve is closed.
- Ensure the inlet pressure indicator indicates an empty cylinder. If not, the combination valve is broken. Do not use it and send it for repair according to chapter 9.
- Connect filling adaptor.
- Slowly open shut-off valve handwheel (anti-clockwise) until fully open - after approx. 1 turn (see indication in picture chapter 5).
- Wait until the whole package for medical gas is completely vented.
- Close shut-off valve (clockwise). Do not use excessive force (max. closing torque is 5 Nm).
- Remove the combination valve from the cylinder using the square surfaces of the combination valve body. Size of square surface is 26 mm.
- Place filling port protective cover back on the combination valve with the gas cylinder pack and store in a way to prevent damage during storage and handling.

⚠ **Use only genuine GCE filling adaptors. Other filling adaptors may damage the non-return valve in the filling port and impact the safety of the product.**

⚠ **Sudden opening could result in a danger of fire or explosion arising from oxygen pressure shocks. Insufficient opening of the shut-off valve could reduce actual flow delivered.**

## 6.2 OPERATIONS PERFORMED BY USER

### 6.2.1 BEFORE USE

**Visual inspection before use:**

- Check the combination valve for damage (incl. label and marking). If it shows signs of

external damages, remove the product from service and suitably identify its status.
- Check the combination valve for contamination. If needed apply the cleaning procedure according to chapter 8.
- Check that the cylinder gas pressure indicator indicates sufficient pressure. If it indicates in the red zone, return the cylinder with combination valve back for filling.

**Leak-tight and functional test before use:**
- Set flow control head (if any) on ZERO position - ensure the flow control head engages correctly.
- Slowly open shut-off valve handwheel (anticlockwise) until fully open - after approx. 1 turn (see indication in picture chapter 5).
- By listening check for leakage (leakage would be heard as characteristic hiss of flowing gas).
- Check that there is a gas flow at each flow control head set position in both clockwise and anticlockwise turning direction (for instance by sound or checking presence of bubbles in a humidifier).
- Close the shut-off valve (clockwise). Do not use excessive torque (max. closing torque is 5 Nm).
- Reset flow control head to ZERO position and ensure flow control head engages correctly.
- For combination valve fitted with pressure outlet, ensure it is in working condition by connecting and disconnecting quick-coupler probe.

### 6.2.2 USE OF COMBINATION VALVE

#### 6.2.2.1 Use of combination valve flow outlet and setting of flow:
- Ensure the flow control head is in position “0”.
- Connect accessories to the flow outlet.
- Slowly open shut-off valve handwheel (anticlockwise) until fully open - after approx. 1 turn (see indication in picture chapter 5).
- Set flow head to required flow position. Ensure flow control head engages correctly.

⚠ **Before connecting any accessory to the flow outlet make sure that the patient is not connected.**

⚠ **Sudden opening could result in a danger of fire or explosion arising from oxygen pressure shocks. Insufficient opening of the shut-off valve could reduce actual flow delivered.**

⚠ **Always ensure that the flow control head has been correctly set and not placed between two settings. Flow control head placed between settings will not deliver correct flow of medical gas.**

⚠ **Common variants of flow control head can have an “end stop” in between the maximum flow position and the zero position. Do not try to apply excessive force on the flow control head when it stops in the maximum flow position (during clockwise rotation) or in zero position (anti-clockwise rotation).**

⚠ **Medical gas flow rate must be prescribed by a doctor.**

#### 6.2.2.2 Use of combination valve pressure outlet
- Ensure the flow control head is in position “0” (if included).
- Slowly open shut-off valve handwheel (anticlockwise) until fully open - after approx. 1 turn (see indication in picture chapter 5).
- Connect accessory to the pressure outlet if not already connected.

⚠ **Before connecting any accessory to the pressure outlet make sure that the patient is not connected and the accessory outlet is secured.**

⚠ **If pressure outlet is to be connected to a medical device that requires high gas flow (for instance pulmonary ventilator that requires gas flow 100 l/min at the minimum pressure 2.8 bar), compare the required flow of connecting medical device with pressure and flow**

**characteristics of the combination valve stated in appendix Nr. 1. To assure sufficient performance (pressure and flow characteristics of the combination valve ) the medical device should not be used if pressure indicator enters the red zone.**

⚠ **Sudden opening could result in a danger of fire or explosion arising from oxygen pressure shocks. Insufficient opening of the shut-off valve could reduce actual flow delivered.**

EN

⚠ **If a pressure outlet as well as a flow outlet are part of the combination valve do not use them simultaneously, especially if pressure in the cylinder is below 50 bar, in could adversely affect the outlet parameters of the combination valve .**

### 6.2.3 AFTER USE

- Close shut-off valve (clockwise). Do not use excessive torque(max. closing torque is 5 Nm).
- Vent pressure from the connected devices.
- Disconnect all connected devices from user outlets.
- Set flow control head on "0" (if included).

## 7. ACCESSORIES

**Accessories connectable to flow outlet:**

- hose connected with mask, cannula or humidifier.

**Accessories connectable to pressure outlet:**

- low pressure hose (working pressure >10 bar), flowmeters, Venturi suction ejectors, lung ventilators.

**Other user accessories:**

- bed hanger, humidifier holder.

**Accessories for filling stations:**

- filling adaptor.

⚠ **Before connecting any accessory or medical device to the combination valve, always check that they are fully compatible with connection features & performances of the product.**

## 8. CLEANING

Remove dirt with a soft cloth damped in oil free soap water & rinsed with clean water. Disinfection can be carried out with an alcohol-based solution (with damped wipes).
If other cleaning solutions are used, check that they are not abrasive and they are compatible with the product materials (including labels) and gas (convenient cleaning solution - i.e. Meliseptol)

⚠ **Do not use cleaning solutions containing ammonia!**

⚠ **Do not expose to water or any other liquid.**

⚠ **Do not expose to high temperature (such as autoclave).**

⚠ **To apply the cleaning solution do not spray it as the spray may enter into the inner parts of combination valve and cause contamination or damage.**

⚠ **Do not use pressure wash as it could damage or contaminate the combination valve .**

⚠ **If the inner parts of the combination valve have been contaminated do not continue to use the combination valve under any circumstances. It must be withdrawn from service.**

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# 9. SERVICE, PRODUCT LIFE TIME AND MAINTENANCE

## 9.1 PRODUCT LIFE TIME

**Serial number and manufacture date**

An eleven-figure serial number stamped on combination valve body consists of the data as follows:
RRRR/MM XXXXX
RRRR: year of manufacture
MM: month of manufacture
XXXXX: sequence number of product
For example: Serial number 2013/03 00521 indicates the combination valve manufactured in 2013, in March, with sequence number 521.

**Product life time and waste management**

End of life time is marked on the combination valve body this way:
RRRR/MM
RRRR: year of lifetime end
MM: month of lifetime end

Maximum life time of this product is 15 years from date of manufacturing.

At the end of the product's life time, the product must be withdrawn from service. The provider of the device shall prevent the reuse of the product and handle the product in compliance with "Directive of European Parliament and Council 2006/12/ES of 5th April 2006 on waste".

## 9.2 REPAIR AND SERVICE OPERATIONS

Repairs and service can be only done by a GCE certified person who also holds all necessary certificates in compliance with national standards for mounting and repair of dedicated gas devices.

For information about a service in your area please contact GCE or distributor of GCE product.

Usually the combination valves can be repaired while fitted on the cylinder.

Repair that do not need to be done by certified personnel include exchange of the below mentioned components:

- guard,
- labels,
- protective covers and separable hose adaptors.

⚠ **All labels on the equipment must be kept in good, legible condition by the provider and the user during the entire product life time.**

⚠ **Use only genuine GCE components.**

Any product sent back to GCE (or GCE authorised centre) for repair or maintenance shall be properly packaged to prevent contamination or damage during storage, transportation and handling.
For product to be repaired, the fault short description or some reference to a claim nr. should be indicated.

# 10. GLOSSARY

| | | | |
|---|---|---|---|
|  | Consult instruction for use |  | Suitable for Hospital care use |
|  | Caution! |  | Suitable for Home care use |

| | | | |
|---|---|---|---|
|  | Keep away from heat and flammable materials. |  | Suitable for Emergency care use |
|  | Keep away from oil and grease! |  | Fragile! |
|  | Keep dry! |  | Weight of product |
|  | Upper and lower humidity level |  | Atmospheric pressure limitation |
|  | Upper and lower temperature limit |  | Use until |
|  | Inlet parameter | SN | Serial number |
|  | Outlet parameter | REF | Reference number |
| $P_1$ | Inlet pressure | LOT | Batch number |
| $P_2$ | Outlet pressure | REF 1 | Reference number |
|  | Manufacturer |  | Take the equipment back for recycling. Do not dispose equipment into unsorted municipal waste. |
|  | Date of manufacture | | |

## 11. WARRANTY

The Standard Warranty period is two years from date of receipt by the GCE Customer (or if this is not known 2 years from time of the product manufacture shown on the product).
The standard warranty is only valid for products handled according to Instruction for use (IFU) and general industry good practice and standards.

**APPENDIX:**
Nr 1 – Technical and performance data
Nr 2 – Quick-coupler features and connecting/disconnecting procedure
Nr 3 – Post Filling Checks

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